IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

THOMAS JOSHUA HOFFERTH, an individual,	§	Civil Action No.: 3:17-cv-01560-MGL
Plaintiff,	§	
vs.	§	
JANSSEN PHARMACEUTICALS, INC.; JANSSEN, L.P.; JOHNSON & JOHNSON; JANSSEN RESEARCH AND DEVELOPMENT, LLC,	§	
Defendants.	§	

MEMORANDUM OPINION AND ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

I. INTRODUCTION

This is an action for various tort-based claims under South Carolina law. The Court has jurisdiction over this matter under 28 U.S.C. § 1332.

Pending before the Court is the motion for summary judgment by Defendants Janssen Pharmaceuticals, Inc., Janssen, L.P., Johnson & Johnson (J&J), and Janssen Research & Development, LLC (JRD) (collectively, Defendants). Having carefully considered the motion, the response, the reply, the record, and the applicable law, it is the judgment of the Court Defendants' motion for summary judgment will be granted in part and denied in part.

II. FACTUAL AND PROCEDURAL HISTORY

Plaintiff Thomas Joshua Hofferth (Hofferth) filed the this action alleging numerous South Carolina tort violations—strict products liability, negligence, failure to warn, breach of an implied warranty of merchantability, breach of express warranty, breach of implied warranty of fitness for a particular purpose, fraud, and negligent misrepresentation—based upon his use of two antipsychotic pharmacological drugs, Risperdal and Invega, produced by Defendants. Hofferth, now twenty-eight years old, was diagnosed with possible bipolar disorder as a child, and during the course of his mental health treatment, his doctor, Dr. Craig A. Stuck (Stuck), prescribed the two medications.

During his treatment Hofferth experienced significant weight gain and was eventually diagnosed with gynecomastia. Gynecomastia is an enlargement or swelling of the breast tissue in males.

Hofferth, during discovery, acknowledged his allegations were limited to the development of gynecomastia purportedly because of his use of Risperdal and/or Invega. Pl. Fifth Supplemental Answers to Defs' First Set of Interrog., Nos. 7-8. Hofferth's claims were further limited when his own causation expert, Dr. Scott Isaacs (Isaacs), conceded the purported side effect, gynecomastia, was caused only by Invega, not Risperdal. Isaacs' Report at 17 ("Thus, after eliminating any potential or contributory causes, . . . , to a reasonable degree of scientific and medical certainty, Invega was the cause of Thomas Hofferth's gynecomastia."); *see also id.* at 14 ("Risperdal did not likely cause Mr. Hofferth's chronic gynecomastia."). Accordingly, the case before the Court concerns the legal implications of Invega's purported causation of gynecomastia in Hofferth.

Defendants filed four motions to exclude the expert testimony of Martin T. Wells (Wells), L. Randolph Waid (Waid), Dr. David A. Kessler (Kessler), and Isaacs, in addition to the motion for summary judgment. The Court denied the motions as to Wells, Kessler, and Isaacs, and granted in part and denied in part the motion as to Waid. The Court is now prepared to rule on the motion for summary judgment.

III. STANDARD OF REVIEW

Rule 56(c) of the Federal Rules of Civil Procedure provides summary judgment "shall be rendered forthwith if the pleadings, depositions, answers to interrogatories and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." The moving party bears this initial burden of informing the Court of the basis for its motions and identifying those portions of the record "which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The Court reviews the record by drawing all inferences most favorable to the party opposing the motion. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

IV. DISCUSSION AND ANALYSIS

Defendants present six separate grounds for summary judgment: 1) Hofferth's claims are time-barred by South Carolina's statute of limitations, 2) the learned intermediary doctrine bars Hofferth's claims, 3) Hofferth fails to establish causation, 4) Hofferth provides deficient evidence to support a failure-to-warn claim and such a claim would be preempted under federal law, 5) Hofferth lacks sufficient evidence to support his breach of warranty claims, and 6) Hofferth's

evidence is insufficient to support his fraud and negligent misrepresentation claims. Defendants additionally assert Hofferth has no legal basis to impose liability against J&J or JRD. The Court will address each argument in turn.

A. Whether Hofferth's claims are time-barred under South Carolina's statute of limitations

South Carolina imposes a three-year statute of limitations on products liability actions. S.C. Code Ann. § 15-3-530(5). The limitations period commences under South Carolina law when "the injured party either knows or should have known by the exercise of reasonable diligence that a cause of action arises from wrongful conduct." *State ex rel. Wilson v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, 777 S.E.2d 176, 198 (S.C. 2015). "[W]here the material facts [for determining the statute of limitations] are in dispute, the issue becomes one for the jury." *Columbia Venture, LLC v. Deberry & Davis, LLC*, 604 F.3d 824, 829 (4th Cir. 2010) (citing *Brown v. Finger*, 124 S.E.2d 781, 786 (S.C. 1962)).

Defendants argue Hofferth failed to be reasonably diligent in investigating his condition prior to the expiration of the limitations period such that he would have had actual notice of his condition, Hofferth's weight gain while on Invega was sufficient notice of a cause of action, and, alternatively, Hofferth had constructive notice or knowledge of his alleged injury prior to the limitations period. Neither party disputes Hofferth visited Stuck in 2013 regarding his weight gain. Stuck's records indicate he planned to check Hofferth's prolactin levels based on Hofferth's "report of gynecomastia." Stuck's 9/3/13 Record at 2.

Nonetheless, Hofferth denies knowledge of his gynecomastia until 2015. *See* J. Franklin Martin, Jr. (Martin) Dep. 103:18-24 (stating he discussed gynecomastia with Hofferth first in 2015 and had never heard Hofferth use the term prior to that discussion); Hofferth Dep. 152:8-15 (stating he had never received the requisite breast exam for diagnosing gynecomastia prior to his 2015

appointment with Martin). Accordingly, there is a genuine issue of material fact as to whether Hofferth exercised reasonable diligence in investigating his condition before the three-year statute of limitations expired. As such, the Court is of the firm opinion this is a question best left for the jury to decide. *See Columbia Ventures*, 604 F.3d at 829 (stating disputes of material facts relevant to a statute of limitations analysis are reserved for the jury).

Further, the Court is unconvinced weight gain per se is sufficient to notify Hofferth of the contraction of gynecomastia, as weight gain could have a variety of significances. Although the statute of limitations fails to require a plaintiff to have knowledge of the extent of the injuries, *Dean v. Ruscon Corp.*, 468 S.E.2d 645, 647 (S.C. 1996) ("[T]he fact that the injured party may not comprehend the full extent of the damage is immaterial."), it does require some knowledge of the potential cause of action, *Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, 777 S.E.2d at 198 (starting the statute of limitations when a party either knows or should have known of the cause of action). Because weight gain can have significance distinct from gynecomastia, Hofferth's weight gain was insufficient, by itself, to infer he should have reasonably known at the time of that weight gain of the existence of his causes of action.

Defendants also argue Hofferth had constructive notice of his injury prior to the lapse of the limitations period. Defendants make two distinct constructive notice arguments: 1) Hofferth had constructive notice of his development of gynecomastia, and 2) Hofferth had constructive notice or knowledge Invega could potentially cause gynecomastia prior to 2015, regardless of his knowledge of the actual condition.

Defendants' argument Hofferth had constructive notice of his gynecomastia centers on Hofferth's 2013 visit with Stuck. Although Defendants are correct the statute of limitations begins prior to the development of "a full-blown theory of recovery," *Snell v. Colum. Gun Exch., Inc.*,

278 S.E.2d 333, 334 (S.C. 1981), it does require knowledge of some injury creating some theory of recovery, *Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, 777 S.E.2d at 198 (stating the statute of limitations period commences only after the plaintiff knew or reasonably should have known of their cause of action). As discussed above, there is a material dispute whether Hofferth, at the 2013 Stuck appointment, was aware of his potential injury. *See* Martin Dep. 103:18-24 (stating he discussed gynecomastia with Hofferth first in 2015 and had never heard Hofferth use the term prior to that discussion); Hofferth Dep. 152:8-15 (stating he had never received the requisite breast exam for diagnosing gynecomastia prior to his 2015 appointment with Martin). Accordingly, this, likewise, is an issue more appropriate for the jury.

Defendants' argument Hofferth had constructive knowledge Invega could cause gynecomastia prior to 2015 is based on the inclusion of gynecomastia as a side effect on the Invega packaging, medical literature noting gynecomastia in patients taking Risperdal, and mass tort litigation alleging Risperdal and Invega caused gynecomastia and weight gain—with the associated publicity and awareness brought on by such litigation. Arguments the Invega/Risperdal label create per se constructive notice have been previously advanced and rejected at the summary judgment stage. *In re Risperdal Litig.*, 223 A.3d 633, 641-47 (Pa. 2019). The same court likewise rejected the argument news coverage, medical journal articles, and the litigation, were sufficient to establish per se constructive notice to the plaintiffs ingestion of the drug caused gynecomastia rather than mere weight gain. *Id.* at 652.

This Court agrees with the analysis of the Pennsylvania Supreme Court. As the Pennsylvania court held, although the pieces of evidence cited by Defendants are potential factors favoring constructive notice, the law requires evidence an individual plaintiff consumed them in a manner as to create constructive notice. Defendants fail to establish Hofferth consumed—much

less understood—the materials in question, and, thus, these materials alone are insufficient to overcome the material dispute of fact as to Hofferth's notice of his claims. Stated differently, these methods, by themselves, are not sufficient per se to establish notice, as they still require plaintiff to have consumed and understood the information. Defendants failed to establish Hofferth consumed, much less understood the significance of, the sources of information cited. As such, they are insufficient to establish notice.

Accordingly, summary judgment is inappropriate based on the statute of limitations and the issue is more apt for jury consideration.

B. Whether the learned intermediary doctrine bars Hofferth's claims

Neither party disputes the applicability of the learned intermediary doctrine to the case at hand. Under the doctrine, as applied to pharmaceutical products liability cases, "the manufacturer's duty to warn extends only to the prescribing physician, who then assumes responsibility for advising the individual patient of the risks associated with the drug or device." *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992). The plaintiff has the burden "to demonstrate that the additional non-disclosed risk was sufficiently high that it would have changed the treating physician's decision to prescribe the product for the plaintiff." *Id.*

Further, if the prescribing doctor "already knew of the risk" associated with the medication at the time of the prescription, despite a lack of a warning, the plaintiff would be unable to meet his burden under the learned intermediary doctrine. *Id.* at 1002. Defendants argue Stuck already knew the risks and his prescribing decision would remain the same even with an additional disclosure of the heightened risk of gynecomastia.

The parties dispute whether Stuck was fully aware of the risk of gynecomastia and its scope at the time of Hofferth's treatment. Although Defendants have established Stuck was aware of the

connection between elevated prolactin and gynecomastia, *see* Struck Dep. 11:12-111:12, 112:7-113:13 (Stuck discussing the connection between elevated prolactin levels and the potential development of gynecomastia), there remains a material dispute of fact as to Stuck's knowledge of the scope of the risk of gynecomastia for patients at the time he prescribed Invega, *see id.* 215:16-24 ("I was aware that there was a general increased risk with use of antipsychotic medications and with Risperdal, but not aware of the age—the specific risk where it's increased in boys."). Accordingly, the issue is more apt for a jury determination.

Defendants further argue Stuck would have made the same prescribing decision even with an additional warning. Defendants identified three separate statements they argue establish Stuck would have made the same prescribing decision despite any additional information. *See* Stuck Dep. 120:7-11 (Stuck agreeing he made a reasonable decision to prescribe Hofferth Invega in 2008); *id.* 122:3-8 (Stuck agreeing as of the date of the deposition he thought it was an appropriate medical decision to prescribe Hofferth Invega in 2008); *id.* 214:4-11 (Stuck stating he did not believe his decision to prescribe Hofferth Invega was inappropriate given the information provided in the course of this litigation).

But, the reasonableness and appropriateness of Stuck's 2008 decision to prescribe Invega is different from whether Stuck would have changed his prescribing decision knowing the additional non-disclosed risk, the standard under the learned intermediary doctrine. *See Odom*, 979 F.2d at 1003 (stating the learned intermediary doctrine requires the plaintiff must establish the additional non-disclosed risk would have changed the treating physician's prescribing decision). This is so because a prescribing decision might still be reasonable or appropriate considering the additional risk, even if the physician would have made a different prescribing decision with the additional information.

A hypothetical demonstrates this principle. Assume there are two competing drugs for a condition, with one drug having a higher efficacy rate, but also a higher rate of side effects. Doctors may have different opinions on the benefits of each drug, and therefore different doctors may make different decisions between the two medications. A doctor's decision to prescribe one of the medications in such a scenario would not render another physician's decision to prescribe the other drug unreasonable or inappropriate. Moreover, although new information about an increase in the rate of a side effect in one of the drugs may alter a prescribing physician's decision on which drug to prescribe to a particular patient, it would be an insufficient basis on which to say the doctor's earlier decision to prescribe that drug was unreasonable or inappropriate.

Hofferth has provided evidence Stuck would have disclosed the additional risks to Hofferth and Hofferth's guardian would have made a different medical decision, if they had had the benefit of having the additional information. *See* Stuck Dep. 215:7-15 (stating Stuck would have explained the increased risk with Invega and would have involved Hofferth and his mother in the decision-making process); *id.* 177:8-15 (stating he would have honored Hofferth's mother's decision to treat Hofferth with another medication). Although South Carolina has not spoken on the matter, other states have allowed such statements by a patient to defeat summary judgment. *See, e.g.*, *Payne v. Novartis Pharm. Corp.*, 767 F.3d 526, 533 (6th Cir. 2014) (stating under Tennessee law a statement from the patient she would not have consented to the drug with the additional risk disclosed was sufficient to defeat summary judgment).

Consequently, there remains a material dispute of fact as to whether Stuck would have made the same prescribing decision. As such, there is a material dispute of fact as to whether Hofferth has met his burden to demonstrate "the additional non-disclosed risk was sufficiently high that it would have changed the treating physician's decision to prescribe the product for the

plaintiff." *Odom*, 979 F.2d at 1003. Accordingly, the learned intermediary doctrine fails to provide sufficient grounds for summary judgment.

C. Whether Defendants are entitled to summary judgment based on a failure by Hofferth to establish causation

Defendants argue Hofferth is unable to establish either general or specific causation, essential elements of his causes of action. Defendants' arguments in the present motion mirror those raised in their motion to exclude Isaacs, Hofferth's causation expert. The Court has already rejected these arguments when it declined to exclude Isaacs's expert testimony.

"[T]he doctrine of the law of the case posits that when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages of the same case." *United States v. Aramony*, 166 F.3d 655, 661 (4th Cir. 1999). Nevertheless, the Court again emphasizes, as it did at the hearing on the motion to exclude, Defendants can use cross-examination to question Isaacs's conclusions and identify any potential flaws in Hofferth's causation argument for the jury. The dispute in facts between Hofferth's causation expert and Defendants, however, is quintessentially a fact-finding issue reserved for adjudication by a jury. Accordingly, it would be inappropriate to grant summary judgment at this time based on causation.

D. Whether Defendants are entitled to summary judgment on Hofferth's failure-to-warn cause of action because Hofferth lacks sufficient evidence to establish such a claim, or, alternatively, because the claim is federally preempted

Defendants first argue Hofferth failed to provide sufficient evidence to adequately establish a failure-to-warn claim because his label expert, Kessler, discusses only the Risperdal label. At the hearing on the motion to exclude Kessler, however, Kessler confirmed his analysis applied to the Invega label, as it suffered from identical labeling deficiencies as those identified in his report. As a result, this Court declined to exclude Kessler's expert testimony. Defendants are free to ask

Kessler at trial about potential differences that may undercut his conclusions, but this issue is insufficient to justify summary judgment. The issue should be reserved for the jury.

Defendants also argue Hofferth's failure-to-warn claim is preempted under federal law. They first argue the Food and Drug Administration (FDA) is the arbiter of drug safety and a company cannot be required to update a drug warning unless it can be done consistent with federal law. They further argue the FDA had previously rejected a proposed modification to the safety labeling for Invega, making a change to the Invega label impossible.

Defendants center their first preemption argument on the principle "the FDA [is] the exclusive judge of safety and efficacy based on information available at the commencement of marketing, [but] . . . states [may] reach contrary conclusions when new information not considered by the FDA develops." *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 41 (1st Cir. 2015). In other words, state tort law is prohibited from imposing additional warning requirements for FDA-approved drug labels unless based on new information not presented to the FDA during the approval process. *Id.* at 43 (finding state tort claims related to drug labeling because the information was known to the FDA at the time of the approval). New information is defined as "data, analyses, or other information not previously submitted to the Agency." 21 C.F.R. § 314.3(b).

Hofferth identified Table 21—a 2002 chart prepared internally by Defendants purportedly demonstrating the risk for gynecomastia in boys using Risperdal was double that of others—as an example of newly acquired information not originally presented to the FDA, required for a state to permissibly impose additional warning requirements. *See Wyeth v. Levine*, 555 U.S. 555, 569 (2009) (stating new analysis or data showing an increased severity or frequency of a risk

constitutes new information permitting states to impose additional disclosure requirements). Defendants counter this new data applied only to Risperdal, not Invega.

As established at the *Daubert* hearing, however, there is sufficient evidence to create a material dispute of fact as to whether Risperdal studies are applicable to Invega. For example, as established at the *Daubert* hearing, Defendants used a number of Ripserdal studies during the FDA-approval process for Invega. Should the jury find Risperdal studies directly applicable to Invega, the studies identified by Hofferth would qualify as new information permitting additional warnings. Accordingly, this is an issue appropriately left to the jury.

Defendants further present an impossibility defense, arguing the FDA had clearly indicated it would have rejected an additional warning. But, "absent clear evidence that the FDA would not have approved a change to" the warnings on a pharmaceutical label, it is inappropriate to "conclude that it was impossible for [a drug company] to comply with both federal and state requirements" in making the change. *Wyeth*, 555 U.S. at 571.

Defendants argue the FDA's rejection of a 2012 citizens' petition by the Sheller, P.C. (Sheller Petition), which alleged inadequacies in labeling for both Invega and Risperdal, indicates the FDA would not have approved any additional risk disclosure and forecloses additional disclosure requirements. A citizens' petition is the mechanism through which a person or community organization can request the FDA issue, amend, or revoke a regulation or order, or take any other administrative action. *See* 21 C.F.R.§ 10.30 (describing the requirements for filing a citizens' petition). The Sheller Petition argued for two changes by the FDA: 1) a complete removal of the pediatric indication for each drug, and 2) a Black Box warning, a warning required for serious or life-threatening risks.

Simply stated, the request in the Sheller Petition is materially different from Hofferth's proposal—which would require Defendants to have acknowledged and explained the increased risk of gynecomastia for adolescent males, as compared to the rest of the population, when taking the medication. The denial of the Sheller Petition fails to clearly establish the FDA would have rejected additional strengthening of the risk disclosures, informing medical professionals about the higher levels of risk of gynecomastia and increased prolactin levels for the medications. Defendants have, thus, failed to meet their burden. *See Wyeth*, 555 U.S. at 571 (requiring clear evidence the FDA would not have approved a change). Accordingly, the Court will deny summary judgment on the failure-to-warn cause of action.

E. Whether Defendants are entitled to summary judgment on Hofferth's breach of warranty claims because Hofferth lacks sufficient evidence to establish such claims

Hofferth raises claims for implied warranty of merchantability, implied warranty of fitness for a particular purpose, and express warranty. Defendants assert Hofferth lacks sufficient evidence to support any of these claims.

Preliminarily, "where the particular purpose for which a product is purchased is also the ordinary or intended purpose of the product, the warranties of merchantability and of fitness for a particular purpose merge and are cumulative." *Soaper v. Hope Indus., Inc.*, 424 S.E.2d 493, 495 (S.C. 1992). Accordingly, the Court will treat both implied warranty claims together.

The Uniform Commercial Code (U.C.C.) contains the test for the implied warranty of merchantability at U.C.C. § 2-314, and South Carolina has adopted the U.C.C. test for the implied warranty of merchantability, S.C. Code Ann. § 36-2-314. Specifically, South Carolina law provides "a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." S.C. Code Ann. § 36-2-314(1). The

statute further states "[g]oods to be merchantable must be at least such as . . . are fit for the ordinary purposes for which such goods are used." *Id.* § 36-2-314(2).

It is undisputed Defendants had knowledge Invega would be used in adolescent populations. When Invega was brought to market, its label contained a risk profile explaining the potential risks to a patient using the drug. The risk profile of a medication is important to its merchantability as it goes directly towards the medical decision to utilize the drug. Hofferth, through Isaacs, has offered evidence the medical approach towards treatment with Invega changes with the additional risk factors. This creates a material dispute of fact as to whether there is a necessary change in utilization of Invega, especially in adolescent male populations, and whether that change would undermine the merchantability of the drug as presented at the time it was prescribed to Hofferth. These material disputes of fact preclude summary judgment, with the issue left for jury resolution.

Concerning Hofferth's express warranty claim, Defendants argue he has insufficient evidence to bring this cause of action. An express warranty requires an "affirmation of fact or promise . . . made by the seller to the buyer." S.C. Code Ann. § 36-2-313(a).

Hofferth broadly claims to have offered ample evidence of specific express warranties, but the only specific examples the Court can identify are (1) Defendants' studies on Invega and (2) the Risperdal and the Invega labels.

Hofferth's references to studies performed on Invega and Risperdal fail to constitute an affirmation of fact or promise made by the seller to the buyer. Accordingly, studies cannot serve as the basis for an express warranty claim.

As for Hofferth's argument Invega's label serves as a potential source of an express warranty cause of action, the parties dispute whether express warranty claims on FDA-approved

labels are precluded. But, even assuming express warranty claims based on FDA-approved drug labels are allowed, Hofferth has failed to provide competent evidence the Invega label gives rise to such a claim.

Invega's label contains a singular reference to gynecomastia, warning "Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported in patients receiving prolactin-elevating compounds." 2006 Invega Label at 11. There is no dispute between the parties that this statement is true. And, no potentially withheld information about the risk can serve as a basis for such a claim, as it would fail to be affirmation of fact or promise . . . made by the seller to the buyer." S.C. Code Ann. § 36-2-313(a). Accordingly, Defendants' studies and the Invega label are insufficient to support a cause of action for express warranty. Consequently, summary judgment is appropriate on this claim.

F. Whether Defendants are entitled to summary judgment on Hofferth's fraud and negligent misrepresentation claims because Hofferth lacks sufficient evidence to establish such claims

Both Hofferth's fraud and negligent misrepresentation causes of action require him to establish Defendants made a material false statement he relied upon which caused him damages. *See Moseley v. All Things Possible, Inc.*, 694 S.E.2d 43, 45 (S.C. Ct. App. 2010) (listing the elements of fraud as a representation, its falsity, its materiality, either knowledge or reckless disregard of its falsity, intent that the representation be acted upon, the hearer's ignorance of its falsity, the hearer's reliance on its truth, the hearer's right to rely thereon, and the hearer's consequent and proximate injury.); *Brown v. Stewart*, 557 S.E.2d 676, 680-81 (S.C. Ct. App. 2001) (listing the elements of negligent misrepresentation as a false representation to the plaintiff by defendant, the defendant having a pecuniary interest in making the statement, the defendant owed a duty of care to communicate truthful information to the plaintiff, the defendant breached that

duty by failing to exercise due care, the plaintiff justifiably relied on the representation, and the plaintiff suffered a pecuniary loss as the proximate result of his reliance).

Defendants assert Hofferth has failed to establish they made any false statements, or, alternatively, Hofferth or Stuck relied on any such statements. An omission, or incomplete information, can serve as the basis of a false statement. *See Thermoid Rubber Co. v. Bank of Greenwood*, 1 F.2d 891, 894 (4th Cir 1924) ("The telling of but part of the truth may sometimes effectually mislead."); *Cox v. Edwards*, 8 S.C. 1, 11 (1876) ("[T]here is misrepresentation if a statement is calculated to mislead.").

There is a dispute of fact as to whether Defendants made any false statements in the Invega label. Hofferth has presented evidence of information withheld from the label he claims makes the warnings in the label incomplete and false. For example, according to Hofferth, there was a potential doubling of the risk to adolescent boys developing gynecomastia. *See* Kessler Report ¶ 286. The label, however, had a sole reference to gynecomastia that failed to directly make this point, *see* 2006 Invega Label at 11 (stating there is a correlation between increased prolactin levels and gynecomastia). It is up to a jury to decide whether this purportedly withheld information amounts to a false representation.

Second, Defendants contend Hofferth has no evidence either he or Stuck relied on any misrepresentations. Under the learned intermediary doctrine, there is an assumption the prescribing physician is relying on the information provided in warning labels. *See Odom*, 979 F.2d at 1003 (stating the manufacturers owe physicians the duty to warn so they can fully advise their patients of the risks of a medication). Further, Stuck has indicated additional information is helpful in creating a diagnostic plan. Stuck Dep. 154:18-20. This is sufficient to create a material dispute of fact over the reliance on any alleged false statements.

Finally, Defendants challenge any connection between the misstatements and any purported injury to Hofferth. As previously discussed, there is a material dispute of fact as to whether Hofferth would have taken Invega with the additional disclosed information. *See* Stuck Dep. 215:7-15 (stating Dr. Stuck would have explained the increased risk with Invega and would have involved Hofferth and his mother in the decision-making process); *id.* 177:8-15 (stating he would have honored Hofferth's mother's decision to treat Hofferth with another medication). Additionally, the question of causation has been reserved for the jury. Accordingly, summary judgment would be inappropriate on both of these claims.

G. Whether JRD and J&J are entitled to summary judgment

Under South Carolina law, products liabilities suits are focused on manufacturers or sellers of the product at issue. *Bragg v. Hi-Ranger, Inc.*, 462 S.E.2d 321, 326 (S.C. Ct. App. 1995) (explaining the level of care required for a seller or manufacturer under either a negligence or strict liability theory of a products liability case). Defendants contend Hofferth lacks any evidence JRD or J&J are manufacturers or sellers of Invega. They further argue it is inappropriate to pierce the corporate veil between J&J and its distinct subordinate corporate entities.

Hofferth provided no evidence JRD was either the direct manufacturer or supplier of Invega. Hofferth, however, does provide evidence of the involvement of Johnson & Johnson Pharmaceutical Research & Development, LLC (JJRD), *see* Martynowicz Dep. 104:4-8 (indicating JJRD was involved in Invega's FDA approvals process); *id.* 158:10-13 (indicating the JJRD was the sponsor for Invega). Both of these facts make it entirely unclear what role JJRD had in the development and manufacturing of Invega. There is some indication within the record JJRD later became JRD. *See id.* 107:3-8 (indicating that JJRD may have become a part of Janssen). This is sufficient to create a material dispute of fact concerning JRD's involvement with the

manufacturing and selling of Invega. Accordingly, the Court will deny summary judgment as to JRD.

Hofferth, rather than claim J&J is the direct manufacturer or supplier of Invega, argues J&J effectively controls all its subordinate corporate entities. He cites to the company's annual report, employees working and moving seamlessly between corporate entities, and the involvement of JJRD in the process of bringing Invega to market.

To establish corporate liability across multiple corporate entities, a plaintiff must demonstrate "more than the various entities' operations are intertwined." *Pertuis v. Front Roe Restaurants, Inc.*, 817 S.E.2d 273, 280 (S.C. 2018). Rather, "[c]ombining multiple corporate entities into a single business enterprise requires further evidence of bad faith, abuse, fraud, wrongdoing, or injustice resulting from the blurring of the entities' legal distinctions." *Id.* at 281.

Hofferth has provided no evidence of any bad faith, abuse, fraud, wrongdoing, or injustice resulting from the blurring of the legal distinction between J&J and JJRD. It is commonplace for companies to establish multiple corporate entities, who maintain individual corporate identity despite close collaboration between the different entities. As discussed above, Hofferth focuses on the involvement of JJRD, *see* Martynowicz Dep. 104:4-8 (indicating JJRD was involved in Invega's FDA approvals process); *id.* 158:10-13 (indicating the JJRD was the sponsor for Invega), but fails to establish sufficient grounds to pierce the corporate veil between J&J and JJRD. There is no evidence J&J is either the manufacturer or supplier of Invega and no legal grounds to pierce the corporate veil. Accordingly, summary judgment is appropriate for J&J.

VI. CONCLUSION

Therefore, based on the foregoing discussion and analysis, it is the judgment of the Court Defendants' motion for summary judgment is **GRANTED** as to Hofferth's express warranty claim, as well as to all causes of action against J&J, and **DENIED** in all other respects.

IT IS SO ORDERED.

Signed this 31st day of March 2020 in Columbia, South Carolina.

s/Mary Geiger Lewis
MARY GEIGER LEWIS
UNITED STATES DISTRICT JUDGE